

# Agrium

Ag Biologicals, New Products  
402-15 Innovation Blvd.  
Saskatoon, Saskatchewan S7N 2X8  
Canada  
Phone: (306) 975-3857  
Fax: (306) 975-3750

Gary Peng, Ph.D.  
Research Scientist & Project Leader  
E-mail: gpeng@agrium.com

July 26, 1998

Dr. Janet Andersen  
Biopesticide and Pollution Prevention Division (7501W)  
c/o Document Processing Desk (APPL)  
Office of Pesticide Programs - 7504C  
U.S. Environmental Protection Agency  
401 M Street (SW), Washington, D.C. 20460 USA

RECEIVED

AUG 20 1998

OPP/BPPD

**Subject:** Registration of a bacterial inoculant, AtEze™ (containing *Pseudomonas chlororaphis* strain 63-28 as the active ingredient), for suppression of soil-borne diseases on greenhouse crops.

Dear Dr. Andersen:

Agrium Inc. (EPA company # 70724) is hereby submitting a Section 3 registration application, including the completed Application Form for Pesticide Registration (8570-1), Confidential Statement of Formulation (8570-4), Data Matrix Sheets, and a proposed product label (5 copies), for the above product to the EPA.

In support of this application, we also enclose three copies of study results and information (14 Volumes in total) to meet requirements detailed in the U.S. FIFRA Guidelines: 40 CFR Part 158 and U.S. EPA Subdivision M for registration of microbial pesticides. The arrangement of this information is outlined in the Data Matrix Sheets. As stated in the enclosed authorization letter, Ms. Wendy Anderson at Agrium US Inc., is the authorized U.S. representative of Agrium Inc.; correspondence regarding this registration application may be sent to her attention.

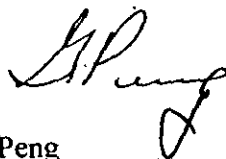
AtEze™ contains a naturally-occurring, non-toxic, and non-pathogenic bacterium, *Pseudomonas chlororaphis* strain 63-28, as the active ingredient for suppression of two important soil-borne diseases. The product is applied as a soil drench to greenhouse ornamental and vegetable crops. Based on its favorable performance in experimental and commercial trials, and on its non-toxic/non-pathogenic character revealed in various toxicology studies, Agrium believes that this product will provide the industry with a new, safe and effective, tool for disease management. It

has potential to reduce the use of conventional chemical fungicides and is compatible with integrated pest management programs. Accordingly, we respectfully request that the review of this application receive a high priority within the Biopesticides Division.

The US EPA has previously registered *Pseudomonas* strains (*P. fluorescens* A506, *P. fluorescens* 1629BS, and *P. fluorescens* NCIB 12089) for uses on many crops. These strains are exempted from tolerance data requirements (40 CFR, Part 180.1114; 1129, and 1145). The species of *P. fluorescens* and *P. chlororaphis* are closely related taxonomically, but unlike *P. fluorescens*, there are no reports of any negative effect on humans or on plants with the latter species. In consideration of the non-toxic/non-pathogenic characteristics of strain 63-28 (details of studies reported in Volume 6-10 of this submission), and the product use pattern (soil drench only), Agrium requests an exemption from tolerance data requirements. Agrium is preparing a check of US\$11,800 to cover the fee for the tolerance review. The check will be sent directly to EPA Headquarters Accounting Operations Branch, Office of Pesticide Program in Pittsburgh, PA in about 2 weeks. A copy of receipt will be mailed to your office at a latter time.

We hope the data and information provided in this package meets the needs of the EPA. Agrium wishes to request a registration decision by April 1999, to allow commercialization of this product in the United States during the summer of 1999. Should you have any questions regarding this application, please contact me at (306) 975-3857 or Wendy Anderson at (303) 804-4426.

Sincerely,



Gary Peng

## DATA MATRIX

### I. PRODUCT CHEMISTRY DATA REQUIREMENT LISTING

<b>PRODUCT NAME:</b> AtEze™		<b>EPA REG. NO. OR FILE SYMBOL:</b> 70724-E		<b>FORMULATOR EXEMPTION ASSERTED:</b> No				
<b>APPLICANT'S NAME AND ADDRESS:</b> Agrium Inc., 402-15 Innovation Blvd., Saskatoon, SK. Canada S7N 2X8 Agrium U.S. Inc., 4582 S. Ulster Street, Suite 1400, Denver, CO 80237		<b>APPLICATION DATE:</b> July 26, 1998		<b>NAME OF ACTIVE INGREDIENT:</b> <i>Pseudomonas chlororaphis</i> strain 63-28				
DATA REQUIREMENTS		SOURCE OF DATA SATISFYING REQUIREMENT						EPA ACCESSION NUMBER (if known)
40 CFR/Subdivision M Guidelines No. (OPPTS Guidelines)	Name of Study	Data Submitted	Volume of Submission	Study Conducted by applicant	Study at Other Institutions	Use of Public Literature	Others (Explain)	
Part 158.740/151A-10 (885.1100)	Product Identity and Disclosure of Ingredients	YES	Vol. 2	YES	YES	YES		44660401
Part 158.740/151A-11 (885.1200)	Manufacturing Process	YES	Vol. 3	YES	YES	YES		44626201
Part 158.740/151A-12 (885.1300)	Discussion of Formation of Unintentional Ingredients	YES	Vol. 3	YES	NO	NO		
Part 158.740/151A-13 (885.1400)	Analysis of Samples	YES	Vol. 4	YES	NO	NO		44626202
Part 158.740/151A-15 (885.1500)	Certification of Ingredient Limits	YES	Vol. 4	YES	NO	NO		
Part 158.740/151A-16 (885.1600)	Physical and Chemical Properties	YES	Vol. 5	YES	YES	YES		44626203
Part 158.740/151A-17 (885.1700)	Submittal of Samples	YES	Vol. 5	NA	NA	NO		

## II. TOXICOLOGY DATA REQUIREMENT LISTING

PRODUCT NAME: AtEze™		EPA REG. NO. OR FILE SYMBOL: <b>70724-E</b>		FORMULATOR EXEMPTION ASSERTED: No			
APPLICANT'S NAME AND ADDRESS: Agrium Inc., 402-15 Innovation Blvd., Saskatoon, SK, Canada S7N 2X8 Agrium U.S. Inc., 4582 S. Ulster Street, Suite 1400, Denver, CO 80237		APPLICATION DATE: July 26, 1998		NAME OF ACTIVE INGREDIENT: <i>Pseudomonas chlororaphis</i> strain 63-28			

DATA REQUIREMENTS		SOURCE OF DATA SATISFYING REQUIREMENT						EPA ACCESSION NUMBER			
40 CFR/Subdivision M Guidelines No. (OPPTS Guidelines)	Name of Study	Data Submitted	Volume of Submission	Study Conducted by Applicant	Study at Other Institutions	Use of Public literature	Others (explain)				
Part 158.740/150A-3, 150A-4, 152A-10, 13. (PR Notice 86-5)	Sensitivity Detection of <i>P. chlororaphis</i> strain 63-28 for Toxicity/Pathogenicity Testing	YES	Vol. 6	NO	YES	NO		44626204			
Part 160/152A-10 (870.1100)	Acute Oral Toxicity/Limit Study of end-use product in Rats	YES	Vol. 7	NO	YES	NO		44626205			
Part 158.740/152A-11 (885.1200)	Acute Dermal Toxicity Study of End-Use Product in Rabbits	YES	Vol. 8	NO	YES	NO		44626206			
Part 158.740/152A-11 (885.2500)	Acute Dermal Irritation Study of End-Use Product in Rabbits	YES	Vol. 8	NO	YES	NO		44626207			
Part 158.740/152A-13 (885.3200)	Acute Intravenous Toxicity/Pathogenicity Study of Active Ingredient in Rats	YES	Vol. 9	NO	YES	NO		44626208			
Part 158.740/152A-14 (870.2400)	Primary Eye Irritation/Infection Study of End-use Product in Rabbits	YES	Vol. 10	NO	YES	NO		44626209			
152A-15 (885.3409)	Hypersensitivity Incidents	NO	Vol. 11	YES	NO	NO		44626209			
Part 160/152A-10 (885.3050)	Acute Oral Pathogenicity Study in Rats	NO	Vol. 12	NO	NO	NO	Rationale for data waiver	ADMIN			
Part 158.740/152A-12 (885.3500)	Acute Pulmonary Toxicity and Pathogenicity Study	NO	Vol. 12	NO	NO	NO	Rationale for data waiver				

### III. NON-TARGET ORGANISMS AND ENVIRONMENTAL SAFETY DATA REQUIREMENT LISTING

<b>PRODUCT NAME:</b> AtEze™		<b>EPA REG. NO. OR FILE SYMBOL:</b> 70724-E		<b>FORMULATOR EXEMPTION ASSERTED:</b> No				
<b>APPLICANT'S NAME AND ADDRESS:</b> Agrium Inc., 402-15 Innovation Blvd., Saskatoon, SK, Canada S7N 2X8 Agrium U.S. Inc., 4582 S. Ulster Street, Suite 1400, Denver, CO 80237		<b>APPLICATION DATE:</b> July 26, 1998		<b>NAME OF ACTIVE INGREDIENT:</b> <i>Pseudomonas chlororaphis</i> strain 63-28				
DATA REQUIREMENTS		SOURCE OF DATA SATISFYING REQUIREMENT						EPA ACCESSION NUMBER
40 CFR/Subdivision M Guidelines No. (OPPTS Guidelines)	Name of Test	Data Submitted	Volume of Submission	Study Conducted by Applicant	Study at Other Institutions	Use of Public literature	Others (explain)	
Part 158.740/154A-16 (885.4100)	Avian Oral Pathogenicity/Toxicity Test	NO	Vol. 13	NO	NO	NO	Rationale for data waiver	A d m i n
Part 158.740/154A-17 (885.4100)	Avian Respiratory Pathogenicity Test	NO	Vol. 13	NO	NO	NO	Rationale for data waiver	
Part 158.740/154A-19 (885.4200)	Freshwater Fish Toxicity and Pathogenicity Test	NO	Vol. 13	NO	NO	NO	Rationale for data waiver	
Part 158.740/154A-20 (882.4240)	Freshwater Aquatic Invertebrate Toxicity and Pathogenicity Test	NO	Vol. 13	NO	NO	NO	Rationale for data waiver	
Part 158.740/154A-23 (885.4340)	Non-target Insect Testing	NO	Vol. 13	NO	NO	NO	Rationale for data waiver	
Part 158.740/154A-24 (885.4380)	Honey Bee Toxicity	NO	Vol. 13	NO	NO	NO	Rationale for data waiver	
Subdivision M, Section 156A-1 and 156A-2	Product Performance	YES	Vol. 14	YES	YES	YES		44626210